NON-TECHNICAL ABSTRACT

No consistently effective therapy exists for adults with metastatic melanoma or for primary or metastatic sarcoma other than surgical extirpation. Currently, few patients with advanced melanoma or sarcoma are cured by surgical removal, and most die within five years of diagnosis. A new technology (particle-mediated gene transfer) uses microscopic gold particles to carry a gene for the natural human cytokine, granulocyte-macrophage colony stimulating factor (GM-CSF), into tumor cells where the gene is expressed without damage to the cell. In mice these transfected tumor cells can be used as a vaccine to induce an immune response against the tumor and lead to rejection of a subsequent tumor challenge.

This proposed phase I trial is designed to study the acute and long-term toxicity of this new gene delivery approach. The anti-tumor response induced by this vaccination strategy will also be studied. Patients with melanoma or sarcoma will undergo surgical removal of a tumor sample which will be enzymatically dissociated, irradiated, and bombarded with gold particles coated with GM-CSF DNA. Patients will then be vaccinated with the transfected tumor cells by intradermal injection. Three and 14 days after the vaccinations, the injection sites will be removed to evaluate the level of production of GM-CSF and other aspects of an immune response. Two dose levels of GM-CSF will be employed in this ascending dosage study.